Australian Government

Department of Health

Therapeutic Goods Administration

2018 GMP Forum

Tuesday, 26 June 2018

PROPOSED PROGRAM(*)

Time	Topic	Speaker	Room
8.30am Registration Marble Foyer			
9.00am	Welcome	**Ben Noyen** – Assistant Secretary, Manufacturing Quality Branch (MQB)	Grand Lodge
9.10am	Introductory remarks	**Adjunct Professor John Skerritt** – Deputy Secretary, Health Products Regulation Group (HPRG)	
9.20am	TGA Fees & Charges	**Ben Noyen**	
9.40am	Overview of TGA's involvement in the International Regulatory Environment	**Jenny Hantzinikolas** – Director, Inspections Section (IS), MQB	
10.10am	GMP Clearance updates - MRA and CV processes - Changes - Improvements - Challenges	**Stephen Farrell** – Assistant Director, Licensing & Certification Section (LCS), MQB	
10.30am MORNING TEA Marble Foyer			
11.00am	Driving a GMP culture to provide supporting evidence of better business outcomes	**Robert Caunce** – Senior GMP Inspector, IS	Grand Lodge
11.45am	Adoption of PIC/S GMP Guide PE009-13 - MQB Strategy - Timeframes - Transitional arrangements	**Matt Davis** - Senior GMP Inspector, IS **Neale Baldwin** – Team Leader & Senior GMP Inspector, IS	

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 02 6232 8444 Fax: 02 6203 1605 Email: info@tga.gov.au
http://www.tga.gov.au

TGA Health Safety Regulation

Time	Topic	Speaker	Room
12.30pm LUNCH Marble Foyer			
CONCURRENT SESSIONS			
(*) For the following sessions, specific details for the listed topics and the allocated speakers are subject to further refinement and change. A final program will be published in early June.			
1.30pm	Expectations with Adoption of the PIC/S GMP Guide PE009-13 Chapter 1 - Pharmaceutical Quality System - Chapter 7 – Outsourced Activities - Annex 1 – Feedback on Draft - Annex 15 – Qualification and Validation - Other specific expectations	**Matt Davis** **Neale Baldwin** **David Rowbury** - Senior GMP Inspector, IS **Emmett Broderick** - GMP Inspector, IS	Grand Lodge
1.30pm **1.50pm** **2.30pm** 3.**10pm**	GMP Obligations for Small and Medium Enterprises (SMEs) - Overview of the SME Assist program - Manufacturing Basics - GMP Clearance Processes - Recalls	**Avi Rebera** – Assistant Secretary, Regulatory Engagement and Planning Branch (REPB) **Greg Orders** - Senior GMP Inspector, IS **Stephen Farrell** **Darika Sowana** - Assistant Director, LCS **Craig Davies** – Director, Recalls and Case Management Section, MQB	Ionic Room
3.30pm AFTERNOON TEA Marble Foyer			

Time	Topic	Speaker	Room
CONCURRENT 'STAND–UP' SESSIONS			
4.00pm	**Group A topics - GMP inspection requirements** 1. Risk based approach to inspection frequency, re-inspection frequency & different product types, including APIs 2. Emerging trends & developments, common inspection deficiencies and other concerns	**Doreene Kohalmi** Senior GMP Inspector, IS **Jenny Hantzinikolas**	Grand Lodge
4.00pm	**Group B topics – SME Education** 1. GMP Clearance processes – common mistakes and TGA code tables 2. NEW Uniform Recall Procedure for Therapeutic Goods	**Stephen Farrell** **Darika Sowana** **Craig Davies**	Grand Lodge
4.50pm	Concluding remarks	**Ben Noyen**	Grand Lodge
5.00pm Meeting close			